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# Oral Submucous Fibrosis and its Dose-Response Relationship with Habit - A hospital based observational study

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### **Abstract**

Purpose: The present study was undertaken to estimate the prevalence of Oral Submucous Fibrosis (OSMF) in and around population of Vadodara. As very few prevalence studies have been carried out on OSMF in Gujarat population, this study aimed at evaluating the association of OSMF with the type, duration and frequency of the habit. While performing the current study, some cases of Unilateral OSMF were also noticed. And as unilateral OSMF is an untouched area in literature, an attempt has been made here to estimate its prevalence.

**Results:** Out of 1, 09,864 subjects; 2107 cases were found to be diagnosed with OSMF. The overall prevalence of OSMF in this study was found to be 1.92%. Using Pearson's Chi-Square test, comparison of habit with gender (p = 0.023) and with different grades of OSMF (p = 0.021) was found to be statistically significant. Also, One Way ANOVA showed statistically significant difference pertaining to the patients' age (p = 0.004) and duration of the habit (p = 0.001) to that of different grades of OSMF. Moreover, the prevalence of unilateral OSMF was found to be 0.32%.

**Conclusion:** There is a strong association of the patients' age and duration of the habit with that of different grades of OSMF. Also unilateral OSMF, an untouched area in literature, can be addressed further with more studies.

**Keywords:** Prevalence, Oral submucous fibrosis, Unilateral, Vadodara, Arecanut

#### Introduction

Oral submucous fibrosis (OSMF), first described by Schwartz in 1952, is a collagen metabolic disorder and a chronic premalignant condition of the oral mucosa. It is a potentially malignant disorder (PMD) and has a multifactorial etiology although, chewing of areca-nut and tobacco are chiefly associated with this disorder in the south east asian populations. It causes significant morbidity and has a malignant transformation rate of about 7-13 %.

Very few prevalence studies for OSMF are carried out in Gujarat population. Also there are no prevalence studies on Unilateral OSMF as well. Moreover, the relation of OSMF to various types of habit and their actual frequency and duration has not been established.

Hence the present study was undertaken to estimate the prevalence of OSMF in and around population of Vadodara. This study also aimed at evaluating the association of OSMF with the type, duration and frequency of the habit; and also to estimate the prevalence of Unilateral OSMF.

This retrospective study shall be amongst one of the epidemiological studies with a large data over the period of 6 years.

## **Materials and Methodology**

(3.9%) cases were diagnosed with Grade-I, Grade-II, Grade-III and Grade-IV OSMF respectively (Table 2).

Overall study population showed maximum cases having the habit of Gutkha/Padiki (n = 981, 46.55%) followed by

**Study Design:** This observational study was carried out in the Department of Oral Medicine and Radiology; after obtaining approval from the institutional ethical committee and review board [CTRI No.: CTRI/2020/02/023507].

Entire Out-Patient Department (OPD) data of 1,09,864 subjects was retrieved from the archives of the department over the period of 6 years - from January 2014 till December 2019; out of which 2107 patients were found to be clinically diagnosed with different grades of OSMF according to the criteria given by Khanna JN & Andrade NN in 1995.<sup>3</sup>

## **Diagnostic Criteria used for Selection of Cases**

**Inclusion Criteria**: Included subjects between the age range of 16 to 70 years. Patients clinically diagnosed with OSMF and having the habit of consuming different forms of tobacco (or tobacco and its products) were included in the study. Also few cases of fibrosis on either side of the oral cavity were found and included. These were recorded as cases of unilateral OSMF.

Patients with no tobacco related habits and without any evidence of OSMF were excluded from the study.

## **Statistical Analysis**

The statistical analysis was done using Statistical Package for Social Science version 16.0 software (SPSS Inc., Chicago, IL, USA) by setting the significance value at p < 0.05.

### **Results**

Out of 2107 OSMF cases; 1646 (78.1%) were males and 461 (21.9%) were females (Table 1). Amongst all these subjects; 747 (35.5%), 867 (41.1%), 410 (19.5%) and 83 Tobacco quid with betel nut (n = 789, 37.44%) and Areca nut/Betel chew (n = 189, 8.97%) (Table 2).

Comparison of habit with gender using Chi-Square test showed that inspite of having unequal habit-wise distribution in both the genders, it was found to be statistically significant (p = 0.023).

Likewise, comparison of habit with different grades of OSMF also showed statistically significant values (p = 0.021) inspite of unequal habit-wise distribution in all the grades of OSMF.

Mean age of all the OSMF cases was found to be 41.21 years, mean duration of habit was found to be 10.86 years, and the mean frequency of habit consumption per day was found to be 4.80 (Table 3).

The overall prevalence of OSMF in the present study was found to be 1.92%; whereas the prevalence of Unilateral OSMF was found to be 0.32%.

Furthermore; one way ANOVA confirmed statistically significant difference amongst means of different groups and within the groups as well, especially pertaining to the patients' age (p=0.004) and duration of the habit (p=0.001) to that of different grades of OSMF (Table 4). Thus age and duration of the habit do have a variable impact on the outcome of OSMF grades.

		GENDER			
II.		F	M	Total	
HABIT	Areca / Betel-nut	54	135	189	
		28.6%	71.4%	100.0%	
	Bidi	15	43	58	
		25.9%	74.1%	100.0%	
	Cigarette	9	23	32	
		28.1%	71.9%	100.0%	
	Gutkha / Padiki	205	776	981	
		20.9%	79.1%	100.0%	
	Snuff	13	25	38	
		34.2%	65.8%	100.0%	
	Tobacco quid with betel-nut	165	624	789	
		20.9%	79.1%	100.0%	
	Bidi, Areca-nut	0	3	3	
		0%	100.0%	100.0%	
	Cigarette, Tobacco	0	17	17	
		0%	100.0%	100.0%	
TOTAL		461	1646	2107	
		21.9%	78.1%	100.0%	

Table 1: Habit wise distribution amongst Male and Female study population

		OSMF GRADES				
I		Ι	II	III	IV	Total
HABIT	Areca / Betel-nut	71	75	33	10	189
		37.6%	39.7%	17.5%	5.3%	100.0%
	Bidi	22	21	14	1	58
		37.9%	36.2%	24.1%	1.7%	100.0%
	Cigarette	10	18	3	1	32
		31.2%	56.2%	9.4%	3.1%	100.0%
	Gutkha / Padiki	368	410	175	28	981
		37.5%	41.8%	17.8%	2.9%	100.0%
	Snuff	8	17	11	2	38
		21.1%	44.7%	28.9%	5.3%	100.0%
	Tobacco quid with betel-nut	255	320	174	40	789
		32.3%	40.6%	22.1%	5.1%	100.0%
	Bidi, Areca-nut	3	0	0	0	3
		100.0%	0%	0%	0%	100.0%
	Cigarette, Tobacco	10	6	0	1	17
		58.8%	35.3%	0%	5.9%	100.0%
TOTAL		747	867	410	83	2107
		35.5%	41.1%	19.5%	3.9%	100.0%

Table 2: Habit wise distribution amongst different Grades of OSMF

Habit		Age	Duration (years)	Frequency per day	
Areca / Betel-nut	N	189	189	189	
	Mean	40.80	9.67	4.46	
	Std. Deviation	14.024	7.877	4.314	
Bidi	N	58	58	58	
	Mean	43.62	13.47	4.29	
	Std. Deviation	13.069	7.406	2.340	

Cigarette	N	32	32	32
	Mean	42.66	10.20	4.72
	Std. Deviation	14.918	9.515	2.556
Gutkha / Padiki	N	981	981	981
	Mean	40.42	10.42	5.05
	Std. Deviation	13.065	8.373	5.210
Snuff	N	38	38	38
	Mean	43.87	13.95	3.32
	Std. Deviation	15.375	11.805	2.028
Tobacco quid with betel-nut	N	789	789	789
	Mean	42.17	11.46	4.69
	Std. Deviation	14.038	8.967	3.717
Bidi, Areca-nut	N	3	3	3
	Mean	33.00	12.67	2.00
	Std. Deviation	9.849	8.737	1.000
Cigarette, Tobacco	N	17	17	17
	Mean	31.41	6.62	5.65
	Std. Deviation	9.247	4.022	4.242
TOTAL	N	2107	2107	2107
	Mean	41.21	10.86	4.80
	Std. Deviation	13.615	8.636	4.475

Table 3: Duration and Frequency of patients' Tobacco related habit consumption

	<del>,</del>	Sum of Squares	df	Mean Square	F	p-value
AGE	Between Groups	3873.304	7	553.329	3.005	.004
	Within Groups	386495.975	2099	184.133		
	Total	390369.279	2106			
DURATION	Between Groups	1828.391	7	261.199	3.532	.001
	Within Groups	155228.145	2099	73.953		
	Total	157056.536	2106			

FREQUENCY	PER Between Groups	225.955	7	32.279	1.615	.126
DAY	Within Groups	41943.305	2099	19.983		
	Total	42169.261	2106			

Table 4: One-way ANOVA

### **Discussion**

OSMF is now accepted globally as an Indian disease, having highest malignant potential than any other oral potentially malignant disorders.<sup>4</sup> Epidemiological evidence strongly indicates the association of the betel quid (BQ) habit with OSMF.<sup>5</sup> Other etiological factors suggested are chillies, lime, tobacco, nutritional deficiencies such as iron and zinc, immunological disorders, and collagen disorders.<sup>4</sup>

The hallmark of this disease is submucosal fibrosis that affects most parts of the oral cavity, pharynx and upper third of the esophagus leading to dysphagia and progressive trismus due to rigid lips and cheeks.<sup>6</sup> The male-to-female ratio of OSMF varies by region.<sup>4</sup>

According to the National Report of Global Adult Tobacco Survey (NRGATS) of India, the current prevalence of smokeless tobacco use is 25.9%. The current study also revealed that the most commonly associated habit is Padiki / Gutkha (n = 981) followed by Tobacco (n = 789) and Areca nut / Betel chew (n = 189). Recent data suggests that prevalence of OSMF in India has increased from 0.03% to 6.42%.

Various epidemiological studies on the prevalence of OSMF have been carried out till now across the globe. Pindborg JJ et~al. in 1965 and Zachariah J et~al. in 1966 had examined 35,000 patients at dental colleges in Lucknow, Bombay, Bangalore, and Trivandrum; and had recorded OSMF percentage prevalences of 0.5% (n = 10,000), 0.5% (n = 10,000), 0.2% (n = 10,000) and 1.2% (n = 5000) respectively. Specifically Shear M et~al. in

1967 who examined 1000 Indians in South Africa found a prevalence of 0.5%. 12

An epidemiological assessment of OSMF by Pindborg JJ et al. in 1969 among 50,915 Indian villagers had shown a percentage prevalence of 0.2 (n = 10,071) in Gujarat, 0.4 (n = 10,287) in Kerala, 0.04 (n = 10,169) in Andhra Pradesh; and 0 to 0.07 (n = 20,388) in Bihar.  $^{13}$ 

Mehta FS *et al.* in 1972 organized an epidemiologic house-to-house survey among 1,01,761 villagers in Maharashtra and established the prevalence of 0.03% for OSMF. <sup>14</sup> In 2004, the prevalence of OSMF was found to be 0.55% (n = 2017) in a hospital based study which was carried out at Ragas dental college, Chennai by Saraswathi TR et al. <sup>15</sup>

Mathew AL *et al.* at Manipal College of Dental Sciences in 2005 showed a prevalence rate of 2.01% (n = 1190) for OSMF;<sup>16</sup> whereas a prevalence rate of 3.39% (n = 6800) was established in 2010 at NIMS dental college, Jaipur by Sharma R et al.<sup>17</sup>

Bhatnagar P *et al.* in Uttar Pradesh in 2010 estimated a prevalence rate of 1.97% (n = 8866) for OSMF<sup>18</sup>; which is in accordance with the present study estimating a 1.92% OSMF prevalence. On the contrary, another survey in Uttar Pradesh conducted in 2013 by Nigam NK *et al.* showed OSMF prevalence of 6.3% (n = 1000).<sup>19</sup>

Furthermore, a study conducted in Vadodara, Gujarat by Joshi M *et al.* in 2013-14 showed an overall OSMF prevalence rate of 1.79% (n = 60,018); which is also in congruence with the current study.<sup>20</sup>

With regards to unilateral OSMF, an evidence-based study was carried out in Gujarat by Ali FM *et al.* in 2014 which showed that out of 267 patients of OSMF, 250 (93.7%) patients had shown evidence of bilateral involvement of fibrous bands and only 17 (6.3%) patients had shown occurrence of unilateral OSMF involving only one side of buccal mucosa. The present study revealed 0.32% prevalence rate for unilateral OSMF. Though there is still a controversy on the occurrence of unilateral OSMF, many such studies will be required in the near future and this necessitates the demand of a lot of literature to understand its pathogenesis. Ultimately a more revised classification based on unilateral OSMF has become the need of an hour.

### Conclusion

The present study estimated 1.92% prevalence of OSMF, whereas prevalence of unilateral OSMF was found to be 0.32%. A strong association was revealed with respect to patients' age, duration of the habit and different grades of OSMF. This epidemiological study will definitely add to the literature, as very less number of prevalence studies have been carried out in Gujarat Population, that too on such a large scale. Besides, unilateral OSMF is an ignored fact in literature, which further needs to be focused.

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